

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

<b>JERRY LANE BIRDSONG and,</b>	)	
<b>BETTY BIRDSONG,</b>	)	
	)	
<b>Plaintiffs,</b>	)	<b>Civil Action No: 3:10-01182</b>
	)	<b>Judge Campbell</b>
<b>v.</b>	)	<b>Magistrate Judge Knowles</b>
	)	
<b>ELI LILLY AND COMPANY and,</b>	)	<b>JURY DEMAND</b>
<b>AMYLIN PHARMACEUTICALS, INC.,</b>	)	
	)	
<b>Defendants.</b>	)	
	)	

**DEFENDANT ELI LILLY AND COMPANY'S  
MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS**

Defendant Eli Lilly and Company ("Lilly"), pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), hereby submits its memorandum of law in support of its motion to dismiss Claims 3 and 6 of Plaintiffs Jerry Lane Birdsong and Betty Birdsong's Complaint for failure to state a claim upon which relief can be granted. Plaintiffs have not alleged facts sufficient to support their Tennessee Consumer Protection Act claim and have not alleged facts with sufficient particularity to state a claim as to their fraudulent misrepresentation claim. Accordingly, Claims 3 and 6 should be dismissed for the reasons described in more detail below.

**I. MOTION TO DISMISS STANDARD**

Dismissal of claims is appropriate under Rule 12(b)(6) when the pleadings fail to allege facts "sufficient to raise a right to relief above the speculative level" and fail to "state a claim to relief that is plausible on its face." *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (internal quotations omitted). Plaintiffs' complaint must allege "more than labels and conclusions, and a formulaic recitation of a cause of action's elements" is not sufficient to survive a motion made pursuant to

Rule 12(b)(6). *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Furthermore, plaintiffs who allege fraud must satisfy an additional requirement of stating with particularity the circumstances constituting the fraud. *Saltire Industrial, Inc. v. Waller, Lansden, Dortch & Davis, PLLC*, 491 F.3d 522, 525 (6th Cir. 2007) (quoting Fed. R. Civ. P (9)(b)). At a minimum, Plaintiffs must “allege the time, place and content of the (misrepresentation) upon which [they] relied.” *Bender v. Southland Corp.*, 749 F.2d 1205, 1216 (6th Cir. 1984). For the reasons set forth below, Plaintiffs fail to allege facts sufficient to state a claim for relief for both their consumer protection and fraud claims.

## **II. FACTUAL BACKGROUND**

Byetta® is an injectable prescription medicine that may improve blood sugar control in adults with type 2 diabetes mellitus. On December 14, 2010, Plaintiff filed a Complaint against Lilly and Amylin Pharmaceuticals (“Defendants”), alleging that “this is an action to recover damages for personal injury sustained by Jerry Birdsong.” Compl. ¶ 8. Plaintiffs’ Complaint alleges that “Defendants failed to warn or inform consumers, such as Plaintiff or Plaintiff’s prescribing physician, of the known defects in Byetta® including significantly increased risk of acute pancreatitis . . . , fraudulently concealed these defects and made misrepresentations to the damage and detriment of plaintiff.” Compl. ¶ 19. The Complaint also alleges, as a “result of Defendants’ omissions or misrepresentations plaintiff Jerry Lane Birdsong suffered acute pancreatitis on December 30, 2009.” Compl. ¶ 20.

On October 12, 2006, however, the Byetta® label was revised to include a warning about several adverse reactions — including acute pancreatitis — observed in patients taking Byetta.®  
Byetta Package Insert, Oct. 12, 2006, at 15, attached as Exhibit A.<sup>1</sup>

On October 16, 2007, FDA issued an alert to healthcare professionals stating that FDA had reviewed 30 postmarketing reports of acute pancreatitis in patients taking Byetta and that an "association between Byetta® and acute pancreatitis" was suspected in some of those cases. FDA Alert, Information for Healthcare Professionals: Exenatide (marketed as Byetta) – 10/2007, Oct. 16, 2007, attached as Exhibit B (cited in Compl. ¶ 11).

On January 1, 2008, the Byetta® label was revised again to include a paragraph-long warning about acute pancreatitis:

Postmarketing cases of acute pancreatitis have been reported in patients treated with BYETTA. Patients should be informed that persistent severe abdominal pain, which may be accompanied by vomiting, is the hallmark symptom of acute pancreatitis. If pancreatitis is suspected, BYETTA and other potentially suspect drugs should be discontinued, confirmatory tests performed and appropriate treatment initiated. Resuming treatment with BYETTA is not recommended if pancreatitis is confirmed and an alternative etiology for the pancreatitis has not been identified.

Byetta Package Insert, Jan. 1, 2008, at 11, attached as Exhibit C (referred to in Compl. ¶11).

Byetta's January 1, 2008, label also included a section entitled "Information for Patients," that instructed physicians that "Patients should be informed that persistent severe abdominal pain, which may be accompanied by vomiting, is the hallmark symptom of acute pancreatitis and

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<sup>1</sup> The Complaint refers to the Byetta prescribing information and FDA Alerts, but fails to cite to the full labeling or Alerts that address acute pancreatitis, or attach the referenced documents. Lilly is attaching the referenced FDA-approved labeling and FDA Alerts and requests the Court to take judicial notice of these documents that were published on the Food and Drug Administration's website. See, e.g., Compl. ¶¶ 11, 12. Exs. A-D, attached hereto. *Autozone v. Glidden Co.*, No. 08-2851, 2010 U.S. Dist. Lexis 94699, at \*9 (W.D. Tenn. Sept. 10, 2010) (When ruling on a Rule 12(b)(6) motion "[t]he Court may also consider 'documents incorporated into the complaint by reference, and matters of judicial notice.'") (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)). Consideration of these documents referenced in the complaint and subject to judicial notice will not convert this motion to dismiss into a motion for summary judgment. E.g., *Shearer v. Adams*, No. 3:09-cv-991. 2010 U.S. Dist. Lexis 100315 at 16 (M.D. Tenn. Sept. 21, 2010).

be instructed to contact their physician if this symptom occurs (see PRECAUTIONS)." Id. at 13.

On August 18, 2008, FDA issued an updated alert to healthcare professionals regarding Byetta®, discussing that it had received reports of patients taking Byetta® and developing hemorrhagic or necrotizing pancreatitis. FDA Alert, Information for Healthcare Professionals: Exenatide (marketed as Byetta) – 8/2008 Update, Aug. 18, 2008, attached as Exhibit D (cited in Compl. ¶ 12).

### III. ARGUMENT

Plaintiffs fail to allege facts sufficient to state a claim for relief for their consumer protection claim and have failed to allege facts with sufficient particularity to support their fraud claim.

A. Plaintiffs' personal injury claims do not fall within the scope of the Tennessee Consumer Protection Act of 1977

Plaintiffs' claim that Defendants violated the Tennessee Consumer Protection Act of 1977, Tenn. Code. Ann. § 47-18-101 *et seq.*, fails on its face as Plaintiffs do not have standing to bring a private right of action under this act. The Tennessee Consumer Protection Act of 1977 allows a private right of action for damages when a person "suffers an ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value" as a result of an unfair or deceptive act of another. Tenn. Code. Ann. § 47-18-109(a)(1). Courts interpreting the Tennessee Consumer Protection Act have held that the scope of the Tennessee Consumer Protection Act does not include claims for personal injury or wrongful death. *Kirksey v. Overton Pub, Inc.*, 804 S.W.2d 68, 73 (Tenn. Ct. App. 1990) ("We must hold that the General Assembly intended for the Consumer Protection Act to be used by a person claiming damages for an ascertainable loss of money or property . . . not in a wrongful death action."); *Howard v. R.J. Reynolds Tobacco Co.*, 2005 U.S. Dist. Lexis 34458 at \*7 (E.D. Tenn. Aug. 25, 2005) ("the

Court must dismiss Plaintiff's claims to the extent he seeks to recover for injuries to his person resulting from [defendant's] alleged violations" of the Tennessee Consumer Protection Act.).

Plaintiffs' complaint does not allege that they suffered "an ascertainable loss of money or property," but rather alleges that they suffered personal injury resulting from Defendants' allegedly improper conduct. (*E.g.*, Compl. ¶¶ 8, 7, 71).<sup>2</sup> Furthermore, Plaintiffs could never advance a claim for "a loss of money or property," as Plaintiffs' complaint alleges that Jerry Birdsong received free samples of Byetta® and, based on this fact, could never claim that Defendants' alleged conduct resulted in a loss of "money or property." (Compl. ¶ 7). Because Plaintiffs' complaint does not support a cause of action brought under the Tennessee Consumer Protection Act, Claim 6 should be dismissed pursuant to Rule 12(b)(6).

B. Plaintiffs' Complaint fails to identify specific facts supporting their fraud claims

Plaintiffs allege that Defendants' conduct constituted fraudulent misrepresentation, but fail to plead with specificity the misrepresentations giving rise to this cause of action. Plaintiffs' complaint does nothing more than to allege generally that Defendants promoted Byetta® and made material representations which Plaintiff relied upon. *E.g.*, Compl. ¶ 50 ("Defendants widely advertised and promoted Byetta® as a safe and effective medication."); Compl. ¶ 51 ("Defendants intentionally failed to disclose" the "risks of use associated with" Byetta); Compl. ¶ 53 ("Defendants' advertisements regarding Byetta® made material representations to the effect that Byetta was a safe and effective treatment . . . Plaintiff relied upon these material representations in deciding to purchase and consumer Byetta® to his detriment.").

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<sup>2</sup> Paragraph 7 of Plaintiffs' complaint alleges that Jerry Birdsong suffered acute pancreatitis on December 30, 2009 and now suffers from chronic pancreatitis. However, Paragraph 71 of Plaintiffs' complaint alleges that "Plaintiff, suffered acute pancreatitis on February 25, 2006, sustained renal failure, and faces a lifetime of sustained physical and financial damage including pain and suffering." Lilly reserves the right to move to dismiss on statute of limitations grounds if the injury did occur in 2006.

Plaintiffs fail to meet the specificity requirements of Rule 9(b) and fail to allege the “time, place and content” of the representations on which they claim to have relied. The Complaint fails to identify even a single specific statement made to Plaintiffs, or even which of the defendants made such a statement. Plaintiffs have not identified any “advertisement,” much less any allegation that Plaintiffs, or the unidentified prescribing physician, ever received, viewed or received any information from Defendants. Plaintiffs’ complaint is simply nothing more than a compilation of generic allegations made against Defendants and is not sufficient to support a fraud claim. The complaint utterly fails to state “with particularity the circumstances constituting the fraud” and therefore fails to comply with pleading requirements of Rule 9(b).

Plaintiffs’ case concerns the adequacy of the Byetta® warning, not whether or not Defendants committed fraud. Plaintiffs’ allegations, in general, are that Defendants failed to adequately warn “consumers” of the risk of pancreatitis associated with Byetta®. Plaintiffs unsuccessfully attempt to mold their generic failure-to-warn allegations into a fraud claim by claiming that Plaintiffs relied upon Defendants’ so-called inadequate warning. Despite allegations claiming that plaintiffs relied on the unidentified Defendants’ advertisements and generic statements, plaintiffs cannot pursue a fraud claim when they cannot articulate a single specific fraudulent statement made to them, or even a specific statement made to the unidentified prescribing physician.

#### **IV . CONCLUSION**

For the reasons set forth above, Plaintiffs’ Claims 3 (Fraudulent Misrepresentation) and 6 (Violation of Consumer Protection Act) fail to state a claim upon which relief can be granted. Lilly respectfully requests that this Court dismiss Plaintiffs’ Claim 3 (Fraudulent

Misrepresentation) and Claim 6 (Violation of Consumer Protection Act) and for all other relief this Court deems appropriate.

Respectfully submitted,

s/Donna L. Roberts

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*\*Admission to appear Pro Hac Vice to be submitted*

*Attorneys for Defendant Eli Lilly and Company*

## **CERTIFICATE OF SERVICE**

I hereby certify that on January 12, 2011, a copy of the foregoing was filed electronically with the Clerk's office by using the CM/ECF system and served electronically and/or via first-class U.S. mail, postage prepaid, upon the parties as indicated below. Parties may also access this filing through the Court's ECF system.

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